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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,535	07/26/2001	Frans Eduard Janssens	JANS-0004	3436

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/27/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/868,535

Applicant(s)
JANSSENS et al.

Examiner
Brenda Coleman

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-15 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other:

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DETAILED ACTION

Claims 1-8 and 10-15 are pending in the application.

Priority

1. Any non-provisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Cross - references to other related applications may be made when appropriate.

“This application is a national stage entry under 35 U.S.C. § 371 of PCT/EP99/10176, filed December 15, 1999.” is suggested.

Specification

2. The spacing of the lines of the claims is such as to make reading and entry of amendments difficult. New application papers with lines double spaced on good quality paper are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

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make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-8 and 10-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The scope of "prodrug" is not adequately enabled. Applicants provide no guidance as how the compounds are made more active *in vivo*. The choice of a "prodrug" will vary from drug to drug. Therefore, more than minimal routine experimentation would be required to determine which prodrug will be suitable for the instant invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-8 and 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 1-7 and 10-15 are vague and indefinite in that it is not known what is meant by the definition of A. There are two different definitions for the variable A where A together with B is -Y-CH=CH-, -CH=CH-Y- or -CH=CH-CH=CH- and A together with Z is S-CH=CH, S-CH₂-CH₂, S-CH₂-CH₂-CH₂, CH=CH-CH=CH or CH₂-CH₂-CH₂-CH₂.

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- b) Claims 1-7 and 10-15 are vague and indefinite in that it is not known what is meant by the definition of Y. There are two different definitions for the variable Y where Y within the definition of -A-B- is -O-, -S- or -NR⁷- and Y within the definition of L is O, S or NH.
- c) Claim 1 is vague and indefinite in that it is not known what is meant by the definition of R⁸ which is not written as a proper Markush grouping. The definition should terminate with an “or”.
- d) Claim 8 is vague and indefinite in that it is not known what is meant by the numeric representation following the third, fourth, fifth and sixth species.
- e) Claim 8 is vague and indefinite in that the nomenclature of the fourth species contains an unmatched close bracket.
- f) Claim 8 is vague and indefinite in that it is not known what is meant by the period which appears at the end of line 11 of claim 8.
- g) Claim 12 is vague and indefinite in that it is not known what is meant by the numeric representation following the excluded species.
- h) “Derivatizing” in claims 14 and 15 implies more than what is positively recited.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2 and 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janssens et al., WO 97/24356. The generic structure of WO 97/24356 encompasses the instantly claimed compounds (see Formula III-a-2-1, page 12) as claimed herein. Example A2b and A2c differ only in the nature of the A-B, R^4 , R^5 , R^6 and Z^1 substituents. Page 2, line 20 through page 3, line 19 defines the substituent A-B as $-Y-CR^7=CH-$, $-CH=CR^7-Y-$, $-CH=CH-CH=CH-$, $-CH=CR^7-CH=CH-$, $-CH=CH-CR^7=CH-$ OR $-CH=CH-CH=CR^7-$; R^4 is hydrogen, C_{1-6} alkyl, halo, ethenyl substituted with carboxyl or C_{1-6} alkyloxycarbonyl, C_{1-6} alkyl substituted with carboxyl or C_{1-6} alkyloxycarbonyl, hydroxy C_{1-6} alkyl, formyl or carboxyl; R^5 is hydrogen, C_{1-6} alkyl, hydroxy C_{1-6} alkyl, Ar^1 or halo; or R^4 and R^5 taken together may form a bivalent radical of formula $CH=CH-CH=CH$ or $CH_2-CH_2-CH_2-CH_2$; R^6 is hydrogen, C_{1-6} alkyl or Ar^1C_{1-6} alkyl; and Z^1 a bivalent radical of formula $-CH_2-$, $-CH_2-CH_2-$ or $-CH=CH-$. Compounds of the instant invention are generically embraced by WO 97/24356 in view of the interchange ability of A-B, R^4 , R^5 , R^6 and Z^1 substituents of the spiro ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for carboxamide for example R^4 as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

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Claim Objections

6. Claim 11 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be stated in the alternative. See MPEP § 608.01(n).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays from 8:30 AM to 5:00 PM, on Tuesdays from 8:00 AM to 4:30 PM, on Wednesday from 11:30 AM to 8:00 PM and on Thursday and Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for “unofficial” purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


Brenda Coleman
Primary Examiner AU 1624
September 24, 2002